



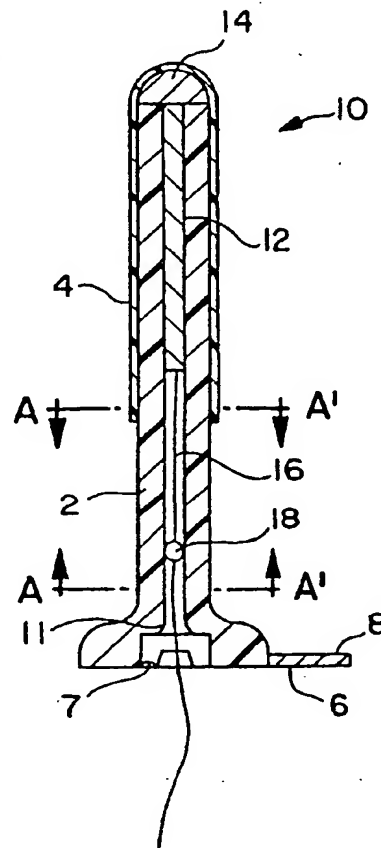
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(54) Title: EXPANDABLE URETHRAL PLUG

(57) Abstract

A urethral plug (10) possessing a contracted diameter for insertion and removal through the orifice of the urethra, and a larger, expanded diameter for blocking the flow of urine in the urethra, bladder neck and bladder. In a first embodiment, the plug (10) comprises a cooperating housing and inner member lying in coaxial engagement. A larger diameter is achieved by mechanical deployment of the inner member, resulting in the changing of the shape of the housing, or in another embodiment, the changing of the shape of the inner member. In a further embodiment the urethral plug comprises a housing comprised of material which undergoes automatic expansion when exposed to temperature. The urethral plug (10) assumes a non-expanded first condition when exposed to a temperature approximately less than that of a mammalian body, and assumes an expanded second condition when exposed to a transition temperature of approximately the body temperature of a mammal.



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EXPANDABLE URETHRAL PLUG BACKGROUND OF THE INVENTION

Field of the invention

The present invention relates to a novel plug which is inserted into the urethra to control urinary incontinence.

Description of the Prior Art

Urinary stress incontinence is defined as the involuntary loss of urine when the pressure within the urethra exceeds the maximum urethral pressure required for maintaining closure. While the problem of urinary incontinence occurs in men and women, it is an affliction especially common in women of child bearing age and beyond.

There are in existence many methods used to address the problem of incontinence. Bladder neck suspension surgery, wherein the neck of the bladder is reduced by suspending the bladder, is perhaps the most desirable way to treat incontinence, especially in younger patients. However, there are numerous risks associated with such surgery, notwithstanding the expense. For some patients, surgery is not recommended for medical or other reasons, and for those with mild incontinence surgery is not an appropriate solution.

Also in existence are a variety of devices for controlling urinary incontinence. Many of these devices require surgery for implantation, and of these surgically implanted devices, there are two distinct types: non-manipulable devices and manipulable devices. One such non-manipulable device, described in United States Patent No. 4,019,499, is a capsule filled with a variable amount of fluid. The capsule is surgically implanted between supporting tissue and the urethra to exert an occluding force thereon. A similar, non-manipulable capsule implant is described in United States Patent No. 3,789,828. However, this device has ties extending therefrom to aid in fiber ingrowth, thus providing mechanical stability to the capsule. One problem associated with this device is the risk of fluid leakage. In ad-

dition to problems with leakage, severe tissue damage may result from the unnatural method in which such devices regulate incontinence.

Other surgically implanted devices exist which are manipulable. These devices provide the wearer with the ability to selectively control the operation of the device via manually operable elements implanted in the tissue surrounding the urethra. United States Patent No. 4,428,365, and United States Patent No. 4,846,784 each disclose an indwelling device having an inflatable chamber with an attached tubing and an inflation bulb. The wearer may manually adjust the pressure exhibited by the inflatable member on the urethra, simply by squeezing the tissue encasing the bulb. These devices, however, often produce thickening and scarring of surrounding tissue, making their usefulness questionable. Additional adverse effects associated with surgically implanted indwelling devices, whether non-manipulable or manipulable in nature, are encrustation, irritation and infection.

There are also known in the art certain indwelling devices that do not require surgical implantation. These devices are inserted by a physician through the urethral orifice and allow the wearer to void either past or through the device. An example of such a device is disclosed in United States Patent No. 4,850,963 in which a physician inserts a bolus of ferromagnetic material through the urethra and into the bladder. The bolus rests at the juncture of the bladder and urethra and is moved for bladder evacuation, by the relative positioning of a magnet across the body of the wearer. However, the bolus may become lodged in an area beyond the reaches of the magnetic force exhibited by the magnet, making the device inoperative. Another example of this type of indwelling device is the prestressed capsule disclosed in United States Patent No. 4,457,299. The capsule is inserted by a physician within the lower interior of the urethra and is set at a prestressed pressure slightly above involuntary pressure. When the urine pressure exceeds the preset pressure of the capsule, the capsule deforms allowing urine to flow around the device. This device, however, has no feature to prevent

migration of the device into the bladder. In United States Patent No. 4,553,533 there is shown a prosthetic urethral sphincter valve which is placed in the urethra and anchored in the bladder. The patient increases his bladder pressure by means of a valsalva maneuver, and holds this pressure while the valve activates. Urine may then pass through the valve with the valve later returning to its closed position. This device is very complicated, expensive, difficult to manufacture and uncomfortable. Another physician-inserted device is disclosed in United States Patent No. 3,797,478. This device has an expandable collar which is inflated after insertion, by an injection of fluid therein. When it is desired to remove the device, the inflated collar is ruptured or serrated, thus expelling the fluid into the wearer's body. Notwithstanding the cumbersome use of this device, there is a risk of infection associated with the release of injection fluid upon removal. Similarly, United States Patent No. 3,841,304 discloses a plug which is inserted by a physician into the urethra and subsequently inflated to block the flow of urine. This device may be left in the body for extended periods. After insertion, the device merely requires repositioning in the urethra to permit bladder evacuation. Such a device leaves the wearer susceptible to infection, as bacteria may be introduced into the urethra during repositioning, or during indwelling time. Also, serious complications can occur upon removal, when a separate wire must be inserted therein. These devices being indwelling, are often cumbersome to the wearer and often cause numerous complications such as encrustation, irritation and infection.

Also known in the art are devices capable of being inserted by the wearer into the urethra. Such devices are removed for voiding, and then reintroduced into the urethra upon completion of bladder evacuation. An example of such a device is the solid-type urethral plug, described by Neilsen, Kurt K. et al., in "The Urethral Plug: A New Treatment Modality for Genuine Urinary Stress Incontinence in Women" J. Urology, vol: 44, p. 1100 (1990). This device consists of one or two solid spheres located along a soft shaft, and a thin, soft plate located at the end of

the shaft. One sphere is located upstream of the maximum urethral closing pressure point, corresponding to the location of the sphincter. In the two sphere embodiment, the second sphere is located with its midpoint at the bladder neck, and is used to assist in reducing urinary flow and pressure transmission to the urethra so that the sphincter can operate. When the patient wants to evacuate the bladder, the plug is removed, evacuation occurs, and a fresh plug is inserted. One problem associated with this device is that the patient must have three urethral closure pressure profiles performed as well as other examinations, before the device is made for the wearer. Additional problems associated with this device include placement difficulties, lack of sealing capabilities associated therewith, inadequate retention thereby allowing expelling and inadequate anchoring by the plate at the meatus. In addition to such problems of inadequate placement, sealing, and retention, is the discomfort associated with insertion and removal, due to the size profile and rigidity of the spheres. The spheres of this device maintain a constant diameter during insertion, and removal. Another "remove-to-void" device is disclosed in United States Patent No. 5,090,424, which comprises a conformable urethral plug. The body of the plug forms a cavity which is in fluid communication with another cavity via a check-valve. Thus, fluid may be pumped into the cavity within the urethra to provide a custom fit. This device, like many others relying on liquids or gels for expansion, relies heavily on a fluid-tight valve in order to maintain retention. Should valve failure occur, evacuation would immediately follow. There is also a chance of fluid leakage into the body of the wearer should rupture of the plug occur.

In view of the above problems associated with the prior art, an easily usable, expandable plug device of a non-fluid construction, which is mechanically actuated, would be desirable to those afflicted with urinary incontinence.

OBJECTS OF THE INVENTION

One object of the invention is to provide a urethral plug

which is easily manipulated by the wearer.

Another object of the invention is to improve the degree of comfort associated with insertion and removal of a urethral plug.

A further object of the invention is to enhance the sealing ability of a urethral plug with the urethra, bladder neck or bladder wall.

Another object of the invention is to stabilize the placement of a urethral plug at the urethral meatus, such that migration into the bladder will not occur.

Still another object of the invention is to reduce the risk of infection to the wearer of a urethral plug .

Still another object of the invention is to provide a method of using a manually deployable urethral plug by patients suffering from urinary incontinence.

It is yet another object of the present invention to provide a method of using a removable-to-void urethral plug which expands automatically without user intervention for retention in the body and to block the flow of urine in the urethra.

These and other objects of the invention are carried out by an expandable urethral plug having a contracted diameter for insertion and removal through the orifice of the urethra, and a larger, expanded diameter for blocking the flow of urine in the urethra, bladder neck and bladder. In a first embodiment, the plug comprises a cooperating housing and inner member lying in coaxial engagement. A larger diameter is achieved by mechanical deployment of the inner member, resulting in the changing of the shape of the housing, or in another embodiment, the changing of the shape of the inner member. In an alternative embodiment the urethral plug comprises a member comprised of material which undergoes automatic expansion when exposed to temperature or liquid. The urethral plug assumes a non-expanded first condition when exposed to a temperature approximately less than that of a mammalian body, and assumes an expanded second condition when exposed to a transition temperature of approximately the body temperature of a mammal. In yet another embodiment, the expanded second condition is achieved when the urethral plug is exposed to natural bodily conditions such as, but not limited to, body

moisture.

In each embodiment, the expansion of the plug causes a balloon to expand, which seals the plug to the urethral, bladder neck and bladder wall. The plug further has a meatal plate for anchoring the plug in the urethra, which prevents migration of both the plug and the cord into the bladder. Removal of the plug for bladder evacuation, may be easily accomplished by pulling a cord. In accordance with a further feature of the invention, there is provided a method for controlling incontinence in humans.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A shows a first embodiment of the urethral plug which has an expansible outer tube, in its contracted configuration.

Figure 1B shows the first embodiment of the urethral plug in its expanded configuration.

Figure 2A shows a second embodiment of the urethral plug which has a braided mesh, in its contracted configuration.

Figure 2B shows the second embodiment of the urethral plug in its expanded configuration.

Figure 3A shows a third embodiment of the urethral plug in its contracted configuration.

Figure 3B shows the third embodiment of the urethral plug in its expanded configuration.

Figure 4A shows a fourth embodiment of the urethral plug, which is thermally expandable, in its contracted configuration.

Figure 4B shows a fourth embodiment of the urethral plug, which is thermally expandable, in its expanded configuration.

Figure 5A shows a fifth embodiment of the urethral plug, comprising a hydrophillic material, in its contracted configuration.

Figure 5B shows a fifth embodiment of the urethral plug, comprising a hydrophillic material, in its expanded configuration.

Figure 6 shows an end view of the meatal plate of the urethral plug of each of the above embodiments.

Figure 7A shows an cross sectional view of the urethral plug.

Figure 7B shows a cross sectional view of an alternate embodiment of the urethral plug.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1A shows the urethral plug of the first embodiment 10, in its contracted configuration. The plug housing comprises a hollow, cylindrical tube 2 which is sized to be easily inserted through the orifice of the urethra. The tube 2 is made from a biocompatible material having characteristics of compressibility. Attached on the periphery thereof either by thermal bonding, laminating or other means, is a sealing membrane, or balloon, 4 which is adapted to rest against the outer tube 2. At the distal end of the tube 2 is a meatal plate 6. The meatal plate 6 is adapted to anchor the urethral plug 10 at the meatus urinarius. To carry out this function of anchoring, the meatal plate 6 is of a thickness sufficient to withstand bodily compression during wear, preferably on the order of 1 millimeter or greater. The meatal plate 6 prevents the plug 10 from passing through the orifice in the urethra ultimately leading into the bladder neck or bladder.

Figure 6 shows an end view of the meatal plate 6, which is the same as the meatal plates to be shown in future embodiments. A portion of the meatal plate 6 is extended so as to form a tab 8 which may be grasped by the wearer for ease of removal. The meatal plate may further aid in maintaining the plug's expanded configuration during wear, by providing means for securing, such as a ball retention socket (not shown). The meatal plate 6 also has an opening 11 therein, lying within the plane of the opening of the outer tube 2.

Referring again to Figure 1A, enclosed within the tube 2 is a support rod 12, which may be a hollow or a solid member. The support rod 12 has a bulb 14 at one end thereof, abutting the proximal end of the tube 2. The bulb 14 functions to hold the support rod 12 within the tube 2. The support rod 12 has a cord 16 attached at its end opposite the bulb 14, which extends

through the tube 2 and beyond the meatal plate 6, thus ensuring that a wearer will always be able to reach the cord 16. On the cord 16 there is preferably formed a knot 18. Although the knot 18 has been used, the attachment of any member having a diameter greater than ball retention socket 7 would suffice. The support rod 12 is preferably stainless steel, the outer tube 2 is preferably formed of a biocompatible thermoplastic material and the balloon 4 is preferably a biocompatible thermoplastic elastomer, such as that sold under the trademark KRATON. However, any biocompatible material may be used for each of the aforementioned elements, as the invention is not to be limited to those named above. Lines A-A' represents the cross sectional view of the tube 2, which will be discussed further with reference to Figures 7A and 7B.

A user inserts the plug 10 while it is in the configuration shown in Figure 1A. Once the plug 10 has been inserted and the meatal plate 6 abuts the meatus urinarius, the plug 10 may be deployed by the wearer, upon which it achieves an expanded configuration, as set forth in Figure 1B. To deploy, the wearer pulls on the cord 16 depending from the support rod 12. By pulling, a downward force is exerted on the cord 16 in the vertical direction, forcing the support rod 12 to slide downwardly in the tube 2 and exert a compressive force against the proximal end of the outer tube 2. The tube 2 thus expands outwardly in the horizontal direction, causing the balloon 4 to expand until the balloon forms a seal with the wall of the urethra, bladder neck or bladder. The wearer then secures the cord by sliding it through a slit (not shown) in the ball retention socket 7 located on the meatal plate 6. This causes the knot 18 to act as a stop, as the knot 18 rests within the socket 7, thereby preventing the tube 2 from returning to its contracted state (Figure 1A).

The plug 10 in an expanded form as shown in Figure 1B, functions to retain and block the flow of urine. When the wearer wishes to remove the plug, a simple tug on the cord 16 in a direction away from the socket 7 will cause the knot 18 to be released therefrom, thus causing the tube 2 to retract to its contracted state of Figure 1A. The tube 2 thereby returns to its

original diameter prior to insertion, making plug removal a comfortable task. Thus, the tube 2 and balloon 4 cooperatively provide an expandable housing and the plug includes means for mechanically expanding the housing and selectively returning the housing to its non-expanded condition.

Figure 2A shows a second embodiment of the urethral plug 110 in its contracted configuration. Tube 102 is formed by a flexible braided mesh 103. Attached on the periphery thereof either by thermal bonding, laminating or other means, is a sealing membrane, or balloon, 104 which is adapted to rest against the tube 102. Enclosed within the tube 102 is a support rod 112, which may be a hollow or a solid member. The support rod has a bulb 114 at one end thereof, fixed to the proximal end of the tube 102. The bulb 114 functions to secure the support rod 112 within the tube 102. The support rod 112 has a cord 116 attached at its end opposite the bulb 114, which extends through the tube 102 and beyond the meatal plate 106, thus ensuring that a wearer will always be able to reach the cord 116. The cord 116 preferably has formed therein a knot 118. Although a knot 118 has been used, the attachment of any member having a diameter greater than ball retention socket 107 would suffice. The support rod 112 is preferably stainless steel, the outer tube 102 is preferably formed of a biocompatible thermoplastic material and the balloon 104 is preferably a biocompatible thermoplastic elastomer, such as that sold under the trademark KRATON. However, any biocompatible material may be used for each of the aforementioned elements, as the invention is not to be limited to those named above. Lines A-A' represent the cross sectional view of the tube 102, which will be discussed further with reference to Figures 7A and 7B.

The user inserts the plug 110 while it is in the configuration shown in Figure 2A. Once the plug has been inserted and the meatal plate 106 abuts the orifice of the urethra, the plug is deployed by the wearer, upon which it achieves the expanded configuration as set forth in Figure 2B. To deploy, the wearer pulls down on the cord 116, in a direction opposite the direction of initial insertion of the device. Thus,

a compressive force is exerted in the vertical direction by the cord 116 on the bulb 114, which is transmitted from the bulb 114 to the tube 102. This force causes the braided mesh 103 to expand outwardly in the horizontal direction. The expansion of the braided mesh forms an oval projection, which projection causes the balloon 104 to expand therewith. The wearer then secures the cord 116 by sliding it through the slit (not shown) in the ball retention socket 107 in the meatal plate 106. This causes the knot 118 to act as a stop, as the knot is brought to rest within the socket 107, thereby preventing the braided mesh 103 from returning to its contracted state as shown in Figure 2A). The balloon thus retains its seal with the urethral, bladder neck or bladder wall and functions to block the flow of urine.

When the wearer wishes to remove the plug, a simple tug on the cord 116 in a direction away from the socket 107 will cause the knot 118 to be released therefrom, thus causing the braided mesh 103 to retract. The tube 102 thereby returns to its original diameter prior to insertion, making plug removal a comfortable task.

Figure 3A shows the plug 210 of the third embodiment of the present invention in its contracted state. An outer tube 202 has a plurality of elongated apertures 201 formed therein. Line A-A' represents the cross sectional view of the outer tube 202 which will be discussed further with reference to Figures 7A and 7B. Attached to the periphery of the outer tube 202, is a sealing membrane, or balloon 204 which is its pre-insertion configuration (Figure 3A), is adapted to rest against the outer tube 202. At the proximal end of the outer tube 202 is an end cap 214. At the distal end of the outer tube 202 is a meatal plate 206 which has a thickness sufficient to prevent compression thereof while the plug is worn. The meatal plate 206 further has a tab 208 and a groove 207 within its upper portion, which acts as a retaining means, to be described in further detail below. The meatal plate 206 also has an opening 211 therein, lying within the plane of the opening of the outer tube 202, through which an inner tube 212 passes.

Referring again to Figure 3A, inner tube 212 fits within the outer tube 202, and is preferably longer than the outer tube 202. The inner tube 212, has a plurality of cuts 213 defining a plurality of elongated segments 215 therein. The inner tube 212 is made from a biocompatible material having a property of compressibility. The inner tube 212 further has a flange 218 at its distal end which aids in securing the inner tube 212 within the outer tube 202 after deployment. The inner tube 212 has a cord 216 attached to its bottom end, which aids in the removal of the plug 210.

The user inserts the plug 210 while it is in the configuration shown in Figure 3A. Once the plug has been inserted and the meatal plate 206 abuts the meatus urinarius, the plug 210 may be deployed by the wearer, whereupon it achieves the expanded configuration set forth in Figure 3B. To deploy, the wearer pushes the inner tube 212 into the outer tube 202, thus causing the proximal end of the inner tube 212 to abut the end cap 214 of the outer tube 202. The wearer continues to push in the vertical direction until the elongated segments 215 of the inner tube 212 expand in the horizontal direction. The elongated segments 215, thus flare-out, until each elongated segment 215 pops through one of the elongated apertures 201 in the outer tube. Upon popping through the apertures 201, the elongated segments 215 cause the balloon 204 to expand. The wearer continues to push until the flange 218 of the inner tube 212 is received in the groove 207 of the outer tube 202, whereupon the two members form a snap-fit thereby locking the elongated segments 215 in a flared configuration.

The balloon 204, having expanded with the flaring of the elongated segments 215, thus forms a seal with the urethral, bladder neck or bladder wall, and thus functions to retain the device and block the flow of urine. When the wearer wishes to remove the plug 210, a simple tug on the cord 216 breaks the snap fit connection between the flange 218 and the groove 207, thereby releasing the flange. This releasing action will cause the elongated segments 215 of the inner tube 212 to retract as the distal end of the inner tube 212 is pulled down and away from abutment

with the end cap 214. Thus, the elongated segments 215 will again lie flush within the outer tube, as shown in Figure 3A, making removal of the plug a comfortable and easy procedure.

The urethral plug assemblies of Figures 4A, 4B, are comprised of a temperature sensitive compound, more particularly a plastic polymer compound, even more particularly, a polyurethane-based polymer compound. The compound is selected for its expansion properties when subjected to temperatures of up to about and including 37°C, which temperatures encompass the range of temperature of a mammalian body, more particularly, a human body. The compound further exhibits properties of shape memory.

The plug of this embodiment is formed from a mold having a hollow center. The shape memory polymer material is blow molded into the maximum expanded shape desired for the plug. The plug in this maximum expanded shape is then drawn through a tubular shaped die heated beyond the transition temperature of the shape memory polymer material, thereby reducing the diameter of the to form a smaller diameter tubular shape, hereinafter referred to as the 'pre-insertion'. Immediately after withdrawing the plug from the die, it is cooled to a temperature below the transition temperature of the shape memory polymer material to maintain its pre-insertion shape. This process produces a plug suitable for insertion into a subject's urethra.

The plug in its pre-insertion shape is now ready for packaging. Packaging means includes encasing the plug in a suitable plastic molded tray designed to maintain the pre-insertion diameter during shipping, as handling and temperature fluctuations above the transition temperature of the shape memory polymer material may follow. Encasing the plug in a gelatin material will also maintain the pre-insertion diameter while the plug is in storage or transit. For those plugs packaged in gelatin, the gelatin simply dissolves when exposed to moisture in the body when inserted by the subject.

Upon insertion of the plug into the urethra of a mammal, the plug is exposed to a temperature gradient which triggers automatic expansion of the device. Remembering the original diameter inherent to its mold shape, the plug begins to expand

from its pre-insertion shape to its mold shape. As it expands toward this end, the plug conforms to the shape and size of the urethra, especially upstream of the sphincter toward the bladder neck. The plug continues to expand diametrically as it continues to realize its mold shape, with the outer limits of expansion defined by the walls of the urethra. Under no circumstances, however, can the plug expand beyond the dimensions of its original mold shape. The shape memory polymer comprising the plug is only capable of expanding and conforming to the environment into which it is placed; it is incapable of exerting a resistive force by itself.

There is no need to custom make the plug for each individual; the subject's urethra is simply measured by a physician to ensure that the proper length and size plug is used. The plug may be manufactured in several lengths and sizes in order to accommodate males and females, adults and children. In its active and operational state, after having been properly sized and used, the plug forms a secure seal with the urethral, bladder neck or bladder wall. The flow of urine through the urethra is thus blocked.

Figure 4A shows the urethral plug 410 in its contracted configuration. Tube 420 is a hollow, thin-walled cylindrical tube which is sized to be easily inserted through the orifice of the urethra. The tube 420 is made from a biocompatible material having characteristics of expansion and compressibility. At the distal end of the tube 420 is a meatal plate 406. The meatal plate 406 is a flanged-type member which is adapted to anchor the urethral plug at the meatus urinarius. To carry out this function of anchoring, the meatal plate 406 is of a thickness sufficient to withstand bodily compression during wear, preferably on the order of 1 millimeter or greater. The meatal plate 406 will prevent the plug from passing through the orifice of the urethra and into the proximal urethra, bladder neck or bladder.

The tube 420 is preferably formed of a biocompatible thermoplastic material. In a preferred embodiment, the tube 420 is made of a known polyurethane-based polymer which provides the plug with shape memory. The unique characteristic of the plas-

tic polymer is its thermally triggered shape memory, which allows the tube 420 constructed of the shape memory polymer to be inserted into the urethra in a relatively compressed and elongated state, and regain a useful shape at a selected temperature, such as human body temperature. The two interchangeable shapes are possible because the shape memory polymer has "elastic memory", that is, a large reversible change in elastic modulus across the glass transition temperature (T_g). Thus, the shape memory polymer offers the unique characteristic of changing from a glassy, more rigid condition to a softer, rubbery condition across the T_g temperature. Such a large change in elastic modulus around the T_g temperature allows for significant deformation in response to temperature changes. An increase in temperature allows the shape memory polymer to become more flexible and, therefore, easily deformable into a new shape. The glass transition of a polymer, such as the shape memory polymer of the preferred embodiment, is depicted below. The diagram demonstrates a first transition from a glassy state to a rubbery state as the temperature increases, and a second transition from a rubbery state to a fluid state as the temperature is allowed to further increase. It is the first transition from the glassy state to the rubbery state that is exploited in the present invention.

Any compound with thermally-triggered shape memory and having a glass transition temperature approximately that of mammalian body temperature can be used in the device of the present invention. A preferred compound is the polyurethane-based shape memory polymer as described above, developed by Mitsubishi Heavy Industries, Ltd. and available from Memry Technologies in Brookfield, CT.

Accordingly, when the urethral plug shown in Figure 4A is subjected to a transition temperature, the relatively rigid plug changes to a second condition in which it is flexible and easily deformable. The plug is now pliable and, remembering its "mold shape plug", able to expand significantly in diameter to conform to the shape of the wearer's urethra. A tight seal with the urethra, bladder neck or bladder wall is formed and the plug is

retained in the wearer's urethra to block the flow of urine.

In accordance with the above discussion, the user inserts the urethral plug of the present invention into the urethra while it is in the configuration of Figure 4A. Once the plug has been inserted into the urethra and the meatal plate 406 abuts the meatus urinarius, the plug is exposed to the heightened temperature of the human body. The temperature increase causes the shape memory polymer comprising the tube 420 to automatically expand outwardly and achieve a protrusion 422 to conform to the size and shape of the wearer's urethra. The shape memory polymer is able to freely adapt and conform to its environment - here, the urethra - because, as already discussed, it is only capable of expanding and conforming to the environment into which it is placed; it is incapable of exerting a resistive force by itself. This important characteristic of the shape memory polymer prevents displacement of the urethra, bladder neck or bladder by the shape memory polymer material.

The plug is now in its expanded configuration 422 as set forth in Figure 4B. As urine accumulates in the bladder, pressure from the accumulating urine builds until the bladder is sufficiently full to exert a downward force on the urine in the bladder neck and urethra. The downward force in turn bears down on the proximal portion of the expanded member of the plug, furthering the diametrical expansion of the proximal portion of the member. The expansion of the plug, in its expanded form, provides a tight seal with the wall of the urethra, bladder neck or bladder to retain the plug in the wearer's body. When the wearer wishes to remove the plug to void, a continuous tug on tab 408 of the meatal plate 406 will cause the rubbery, diametrically expanded member to elongate. The tube 420 is then returned to a smaller diameter and is simply withdrawn from the body. Other means for removal of the plug are contemplated, such as but not limited to, a pulling means, such as a cord, whereby the plug is simply removed by pulling on a cord attached to the plug. The ease with which the shape memory polymer plug allows removal prevents discomfort potentially associated with plug removal.

Figure 5A shows a second embodiment of the automatically ex-

pandable urethral plug 510 of the present invention in its contracted configuration. Similar to the first embodiment discussed above, tube 502 comprises a hollow, thin-walled cylindrical shaft which is sized to be easily inserted through the orifice of the urethra. In an alternative embodiment, the tube 502 may comprise a solid cylindrical shaft. The tube 502 may be made of any inert material suitable for insertion into a mammalian body.

The tube 502 is made from a biocompatible material, preferably from a biocompatible thermoplastic elastomer, more preferably from a biocompatible polyurethane-based polymer. The most preferred tube is injection molded Kraton G, a non-toxic, biocompatible thermoplastic elastomer. Other suitable materials include polyethylene and nylon polymers, and other copolymers similar thereto.

At the proximal end 504 of tube 502, there is an expandable, deformable member 507 which, upon insertion into a mammalian body, is exposed to normal bodily conditions. Exposure to the normal bodily conditions in turn causes the member 507 to expand and achieve its expanded configuration, as shown in Figure 5B.

The member 507 may be sponge or any suitable absorbent hydrophillic material. The expandable, deformable member 507 may be attached to the tube 502 by an adhesive, a collar, thermal bonding, or any attaching means suitable for the materials selected for the member 507. The bodily conditions which affect the member 507 are temperature (as in the shape memory material device); moisture; pH gradations; and/or other such conditions that act on and expand the member 507.

At the distal end 505 of the tube 502 is a meatal plate 506 which, as in the aforementioned embodiment, is a flanged-type member with a thickness sufficient to prevent compression by the urethra during insertion and wear, preferably on the order of 1 millimeter or greater. Additionally on the meatal plate is a tab 508 for ease of removal. Tab 508 is instructive only and can be substituted by other removal means such as, but not limited to, a cord 510 attached to the inside of the tube 502 and extending downwardly through the opening 509 in the meatal plate. Any other such adaptation sufficient to allow removal of the device

by a simple, continuous pulling by the subject, without tools or undue force, is equally contemplated.

The expandable, deformable member 507 has a pre-insertion shape which is sufficiently sized to allow easy insertion into the urethra of a mammalian body, more particularly, a human body. Once inserted, natural conditions in the body cause expansion, preferably diametrical expansion, of the member 507. In one embodiment, the member would be a sponge secured to the tube 502 by any of, but not limited to, the aforementioned attaching means. Upon insertion of the plug into the body, the sponge is exposed to and absorbs moisture naturally present in the body and expands diametrically, thereby forming a secure seal with the urethral, bladder neck or bladder wall of the body. As in the urethral plug comprised of the shape memory polymer material, the urethral plug of this embodiment also expands diametrically until it meets with resistance from the walls of the urethra, bladder neck or bladder. The member 507 maintains its expanded state until acted upon by the wearer, for instance, when voiding is desired. The diametrically expanded member is sufficiently soft and deformable so as to respond to the downward pressure exerted by the wearer's pulling on the tab 508 or other pulling means. A continuous tug on tab 508 of the meatal plate 506, or on cord 510, will cause the expanded member 507 to elongate, as it meets tissue resistance. The plug is then returned to a smaller diameter and is simply withdrawn from the body.

Figure 7A shows a cross sectional view of the urethral plug along line A-A of the preferred embodiments set forth above. Tube 300 represents the diameter of outer tubes 2, 202 of Figures 1A and 3B, and as applicable to the embodiments of Figures 2A, 4A, 5A the diameter of the tubes 102, 420, and 502, respectively. Figure 7B shows an alternate embodiment, along line A-A, of the above mentioned tubes, in cross section. As shown, the diameter of tube 700 is not constant but variant as shown by the curved indentations 702 on the periphery. The indentations 702 provide enhanced surface area by which the plug may more readily adapt to the urethral wall. Such enhanced sealing ability of the plug, means a better fit for the wearer.

The above and other features of the invention, including various novel details of construction and combinations of parts, will now be more particularly described with reference to the accompanying drawings and pointed out in the claims. It will be understood that the particular devices embodying the invention are shown by way of illustration only and not as limitations of the invention. The principles and features of this invention may be employed in various and numerous embodiments without departing from the scope of the invention.

What is claimed is:

1. A plug for use in the urethra to control urinary incontinence, comprising:

a member adapted to possess a contracted diameter during insertion through the orifice of the urethra, and an expanded diameter following insertion,

means for mechanically expanding said member,

means for anchoring said member at the urethral meatus so as to prevent migration thereof.

2. A plug for use in the urethra to control urinary incontinence according to claim 1, wherein said means for mechanically expanding is user-actuatable.

3. A plug for use in the urethra to control urinary incontinence according to claim 1, wherein said means for mechanically expanding is automatically-actuatable.

4. A plug for use in the urethra to control urinary incontinence according to claim 1, further comprising, means for reversing the expansion of said member.

5. A plug for use in the urethra to control urinary incontinence, comprising:

an expandable housing,

means for mechanically expanding said housing,

whereby a manual force on said means for mechanically expanding causes said housing to expand longitudinally.

6. The plug of claim 5, said means for mechanically expanding further comprising a rod-like member positioned within said expandable housing.

7. The plug of claim 5, further comprising a balloon attached to said housing, wherein said balloon is adapted to expand therewith.

8. The plug of claim 6, wherein said rod-like member further comprises a tube.
9. The plug of claim 6, wherein said rod-like member further comprises a cord.
10. The plug of claim 6, wherein said rod like member further comprises means for anchoring, wherein said means for anchoring is positioned externally to said housing.
11. The plug of claim 10, wherein said means for anchoring comprises a bulb.
12. The plug of claim 10, wherein said means for anchoring comprises a knot.
13. The plug of claim 5, wherein said expandable housing comprises a braided mesh.
14. The plug of claim 5, wherein said housing further comprises a meatal plate having a thickness sufficient to withstand compression by the urethra.
15. The plug of claim 5, wherein said housing further comprises curved indentations on the periphery thereof.
16. The plug of claim 6, wherein said rod-like member further comprises curved indentations on the periphery thereof.
17. A device adapted to be inserted in the urethra for controlling urinary incontinence, comprising;
 - a housing having apertures therein and an endcap at a distal end thereof,
 - a tube having a tip adapted to abut said endcap, and a plurality of expansible elongated members formed along a portion of said tube, said tube lying coaxially within said housing such that each of said expansible elongated members are disposed in

line with said apertures, such that abutment of said distal tip with said endcap protracts said elongated members through said apertures.

18. The device of claim 17, wherein said apertures further define latitudinally spaced openings in said housing.

19. The device of claim 17, wherein said housing further comprises a cord emanating from said endcap.

20. The device of claim 17, wherein said tube further comprises a meatal plate.

21. The device of claim 20, wherein said meatal plate has a thickness sufficient to withstand compression by the urethra.

22. The device of claim 17, wherein said housing further comprises curved indentations on the periphery thereof.

23. A plug for use in the urethra to control urinary incontinence comprising:

a first tube,

a second tube extending coaxially with said first tube, wherein said second tube is adapted to expand to a diameter greater than a diameter of said first tube,

a cord, wherein a portion of said cord is positioned within said first tube and said second tube, respectively, said cord having means for anchoring, wherein said means for anchoring is attached to said second tube.

24. The plug of claim 23, further comprising a balloon means for expansion with said second tube.

25. The plug of claim 23, wherein said first tube further comprises a bulb extending from an end thereof.

26. The plug of claim 23, wherein said second tube further com-

prises a meatal plate.

27. The plug of claim 23, wherein said second tube further comprises indentations along the periphery of the tube adapted to seal the tube along the urethral wall.

28. The plug of claim 23, wherein said first tube has apertures defined therein.

29. The plug of claim 28, wherein said second tube has elongated members defined thereon.

30. The plug of claim 23, wherein said second tube further comprises an expandable mesh.

31. The plug of claim 23, wherein said first tube further comprises a meatal plate.

32. The plug of claim 23, wherein said first tube further comprises indentations along the periphery thereof adapted to seal the tube along the urethral wall.

33. A removable plug for use in the urethra to control urinary incontinence comprising an expandable member, said member being adapted to assume a first condition, prior to insertion of said plug into a human body, in which said member is relatively rigid and substantially tubular in configuration, and being further adapted to automatically assume a second condition upon insertion in the human body and exposure to bodily conditions therein, in which said member is flexible and expandable.

34. The plug of claim 33, wherein said member further comprises a meatal plate.

35. The plug of claim 33, wherein said meatal plate has a thickness sufficient to withstand compression by the urethra.

36. The plug of claim 35, wherein said thickness is at least 1 millimeter or greater.

37. The plug of claim 33, wherein said member in said second condition conforms to the shape of said human body's urethra, bladder neck or bladder.

38. The plug of claim 33, wherein said member is comprised of a material which in said first condition, prior to insertion of said plug into the human body, indefinitely retains said rigidity and said tubular configuration, and which, following insertion of said plug into the human body, assumes automatically without user intervention said second condition in which said member is greatly expanded relative to said first condition.

39. The plug of claim 38, wherein said material comprises a plastic polymer.

40. The plug of claim 39, wherein said plastic polymer comprises polyurethane.

41. The plug of claim 38, wherein said material is an absorbent, hydrophillic material.

42. The plug of claim 41, wherein said absorbent, hydrophillic material is sponge.

43. The plug of claim 33, wherein said member is round in cross-section.

44. The plug of claim 43, wherein said member further comprises radiused grooves in cross-section.

45. The plug of claim 33, further comprising means for removal of said plug.

46. The plug of claim 45, wherein said means for removal is a

tab.

47. The plug of claim 45, wherein said means for removal is a cord.

48. A method of using a urethral plug comprising;

- a) providing a urethral plug comprising; an outer tube, a balloon attached, and a member,
- b) inserting said plug into the urethra,
- c) pulling said member away from the urethra after said plug is inserted,
- d) expanding said outer tube and balloon until the flow of urine is blocked, by discontinuing pulling of said member.

49. A method of using a urethral plug according to claim 48, further comprising:

- e) exerting a manual force on said member, in a direction away from said plug for retraction and removal of said plug.

50. A method of using a urethral plug comprising;

- a) providing a urethral plug comprising; an outer tube having apertures therein and an end cap at a distal end of said outer tube, a balloon attached to said outer tube, an internal tube having elongated members formed thereon and a cord attached to said inner tube,
- b) inserting said plug into the urethra,
- c) pushing said inner tube into abutment with said end cap of said outer tube,
- d) compressing said elongated members of said inner-tube via the continued pushing of said inner tube as in step c)
- e) popping said elongated members through said apertures in said outer tube,
- f) expanding said balloon via the popping of said elongated members in step e).

51. The method of using a urethral plug according to claim 50 further comprising:

- g) pulling said cord for retraction of said outer tube and removal of said plug.

52. A method for preventing an unwanted discharge of urine comprising the following steps:

- (a) providing an expandable plug which can be inserted into a urethra, bladder neck or bladder of a mammal;
- (b) inserting the expandable plug into the urethra, bladder neck or bladder of the mammal;
- (c) maintaining the plug in the urethra, bladder neck or bladder to permit expansion of the plug, thereby retaining the plug in the urethra, bladder neck or bladder and restricting the flow of urine from the bladder through the urethra; and
- (d) removing the plug from the urethra, bladder neck or bladder to discharge the urine, which discharge could not be accomplished without said removing of said plug.

53. A method for preventing an unwanted discharge of urine according to claim 52, wherein expansion of the plug according to step (c) is carried out automatically in response to exposure to temperature in a predetermined range.

54. A method for preventing an unwanted discharge of urine comprising the following steps:

- (a) providing a removable device including an expandable member which can be inserted into the urethra, bladder neck or bladder of a mammal;
- (b) inserting the removable device into a urethra, bladder neck or bladder of the mammal;
- (c) maintaining the removable device in the urethra, bladder neck or bladder to allow expansion, automatically without user intervention, of the member, thereby retaining the device in the urethra, bladder neck or bladder and restricting the flow of urine from the bladder through the urethra; and

(d) removing the device from the urethra, bladder neck or bladder to discharge the urine, which discharge could not be accomplished without said removing of said plug.

55. A method for preventing an unwanted discharge of urine according to claim 54, wherein expansion of the plug according to step (c) is carried out automatically in response to exposure to moisture.

56. A method for preventing an unwanted discharge of urine comprising the following steps:

(a) providing an expandable plug which can be inserted into a urethra, bladder neck or bladder of a mammal;

(b) inserting the expandable plug into the urethra, bladder neck or bladder of the mammal;

(c) maintaining the plug in the urethra, bladder neck or bladder,

(d) mechanically expanding the plug, thereby retaining the plug in the urethra, bladder neck or bladder and restricting the flow of urine from the bladder through the urethra;

(e) reversing the expansion of the plug, and

(f) removing the plug from the urethra, bladder neck or bladder to discharge the urine, which discharge could not be accomplished without said removing of said plug.

57. The method for preventing an unwanted discharge of urine according to claim 56, wherein said mechanically expanding step (c) is carried out by manually pulling a cord in a direction away from the urethra.

58. The method for preventing an unwanted discharge of urine according to claim 56, wherein said mechanically expanding step (c) is carried out by manually pushing a tubular member in a direction towards the urethra.

59. A method for preventing an unwanted discharge of urine comprising the following steps:

(a) providing a removable device including an expandable member which can be inserted into the urethra, bladder neck or bladder of a mammal;

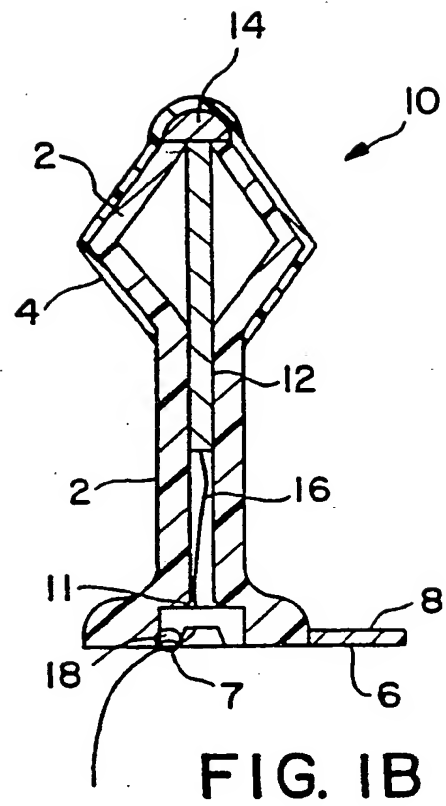
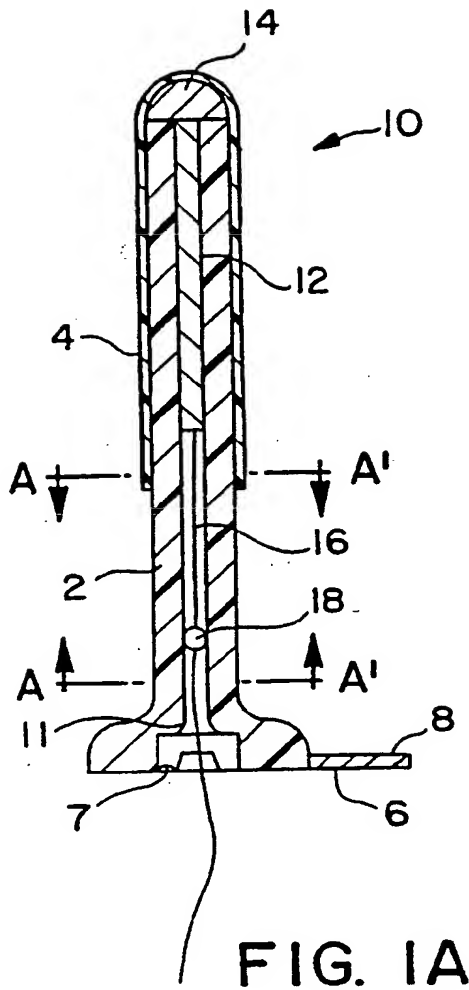
(b) inserting the removable device into a urethra, bladder neck or bladder of the mammal;

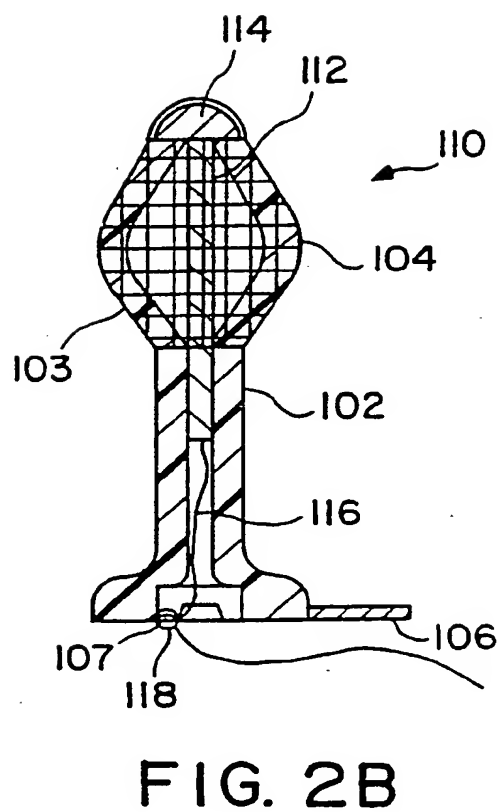
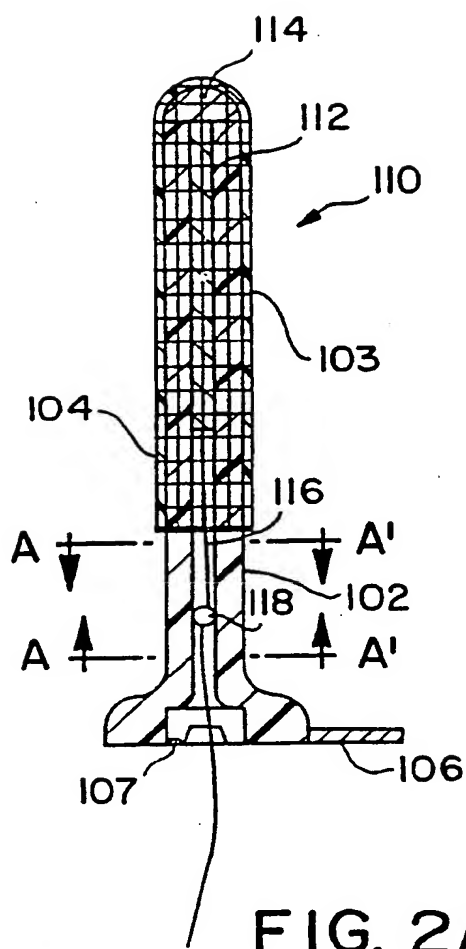
(c) maintaining the removable device in the urethra, bladder neck or bladder,

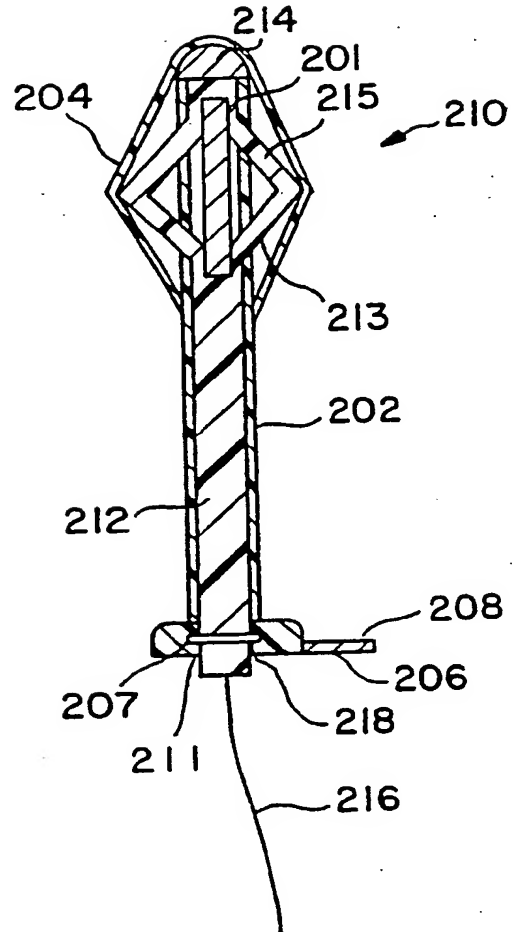
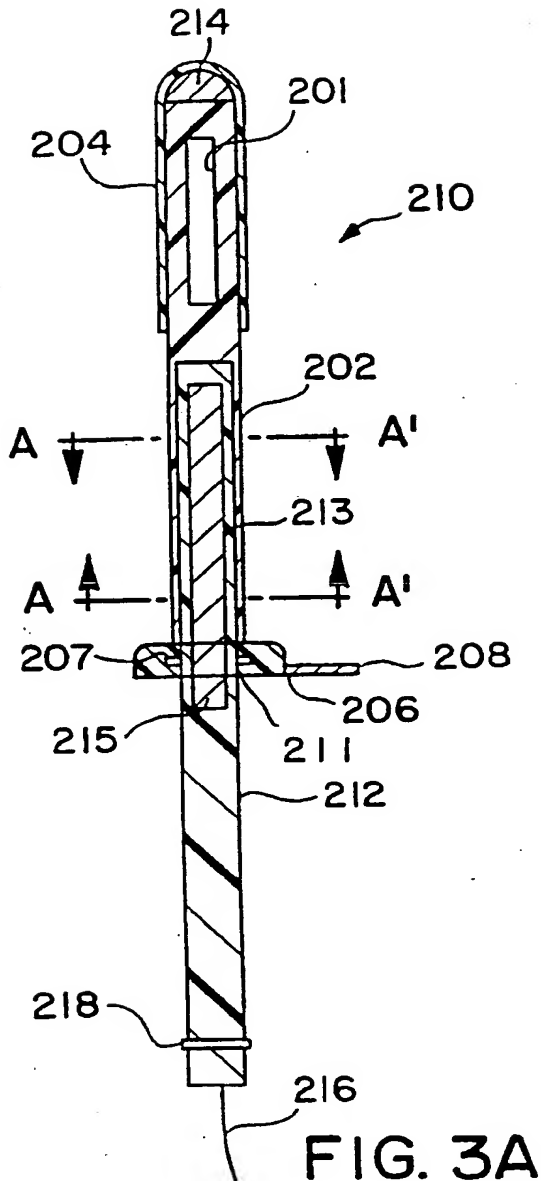
(d) mechanically expanding said device, thereby retaining the device in the urethra, bladder neck or bladder and restricting the flow of urine from the bladder through the urethra; and

(e) removing the device from the urethra, bladder neck or bladder to discharge the urine, which discharge could not be accomplished without said removing of said plug.

60. The method for preventing an unwanted discharge of urine according to claim 59, wherein said step (e) further comprises reversing the expansion of said device prior to removing the device from the urethra.







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FIG. 4A

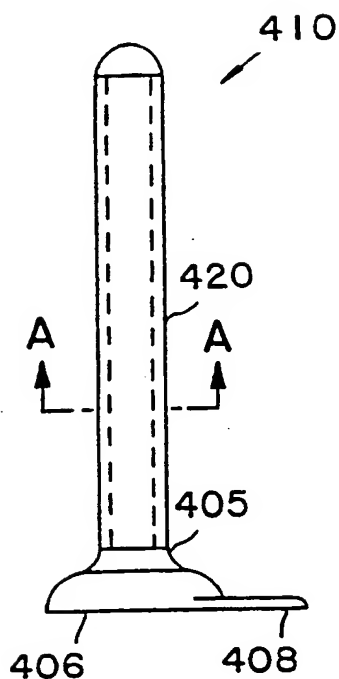


FIG. 4B

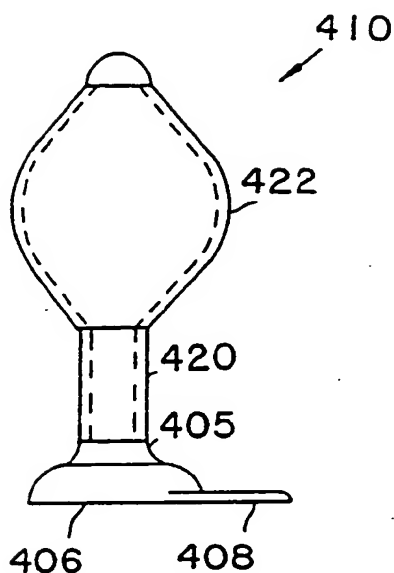


FIG. 5A

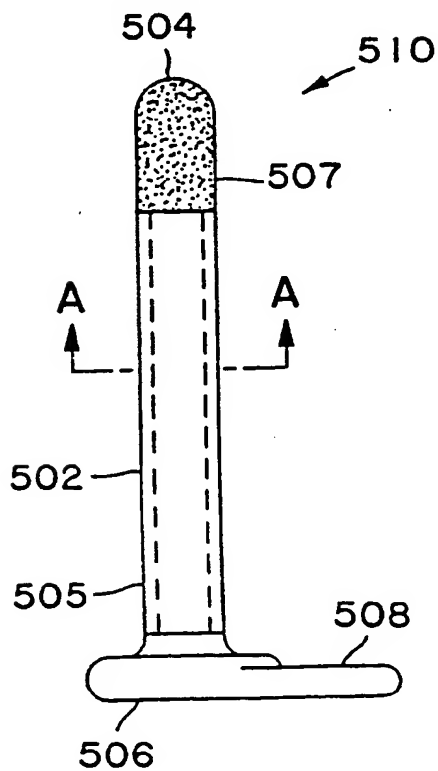
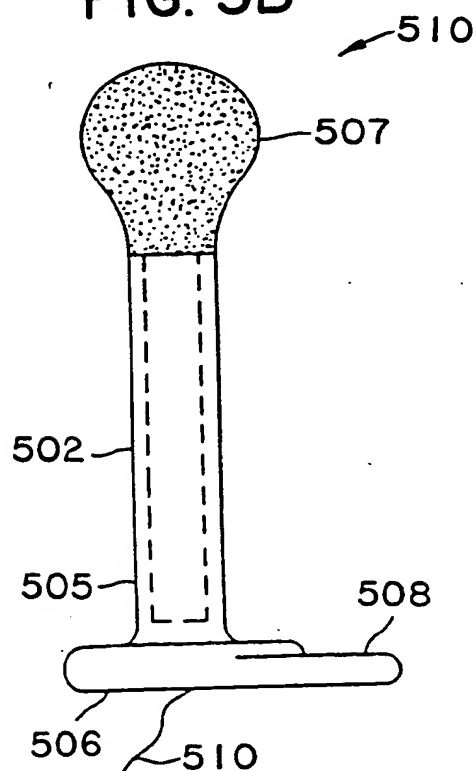


FIG. 5B



SUBSTITUTE SHEET (RULE 26)

FIG. 6

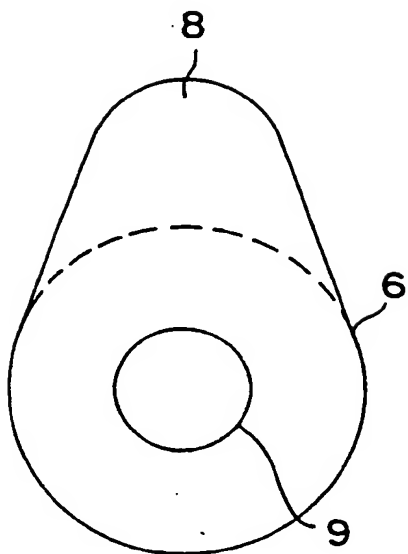


FIG. 7A

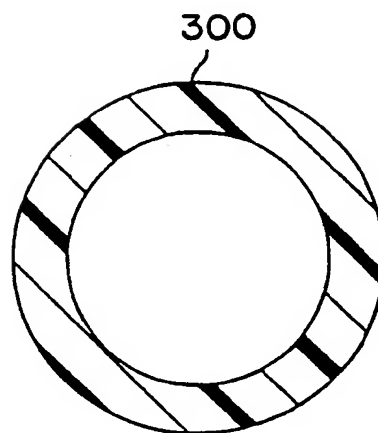
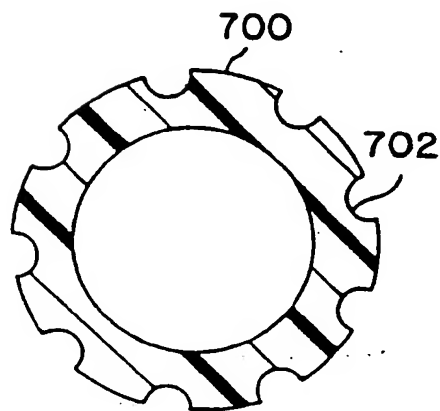


FIG. 7B



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/05536

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 5/48

US CL :128/885

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/885, 886, Digest 25; 600/29-31;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 3,841,304, (JONES), 15 October 1974. See the entire document.	1, 2, 4, 5, 7, 8, 10, 11, 14-16, 48, 52, 54, 56, 58-60 ----- 3, 9, 13
X --- Y	WO, A, 88/10106, (WEST), 29 December 1988. See the entire document.	33, 38-47 ----- 3, 9, 13

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

24 JUNE 1994

Date of mailing of the international search report

19 AUG 1994

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Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/05536

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,846,784, (HABER), 11 July 1989. See the entire document.	1, 2, 4, 5, 7, 8, 10, 11, 14-16, 48, 52, 54, 56, 58-60